THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR PANADOL BABY & INFANT (PARACETAMOL 120MG/5ML) SUSPENSION

Version number 1.0
28 August 2023

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1. Introduction

Panadol Baby & Infant is pink or dark pink, viscous liquid with crystals presents in suspension contains Paracetamol 120mg per each 5 mL. Paracetamol has both analgesic and antipyretic effects. However, it does not have an anti-inflammatory effect. The effect appears to involve inhibition of the enzyme prostaglandin synthetase, but just the lack of an anti-inflammatory effect cannot be explained by this. It is possible that the distribution of paracetamol throughout the body and thus the place where the inhibition of prostaglandin synthetase takes place may be involved. The advantage of paracetamol is that a number of adverse effects characteristic of NSAIDs are entirely or mostly absent for paracetamol. Therefore, paracetamol is a good alternative to NSAIDs for the treatment of pain. Panadol Baby & Infant is approved in Tanzania for use in children between 1 month to 5-years.

1.1 Product details

Registration number	TAN 23 H 0284
Brand name	Panadol Baby & Infant
Generic name, strength, and form	Paracetamol 120mg/5ml
ATC classification	N02BE01, Other Analgesics and Antipyretics
Distribution category	POM
Country of origin	India
Associated product	N/A
Marketing Authorization Holder	GlaxoSmithKline Limited Likoni Road P.o.Box 78392-00507 Nairobi
Local Technical Representative	JD pharmacy limited. P.O.BOX 1899 Dar es salaam

1.2 Assessment procedure

The application for registration of Panadol Baby & Infant was submitted on 08/09/2021. The product underwent full assessment. Assessment was completed in 3 (three) rounds of evaluation and the product was registered on 01 June 2023.

1.3 Information for users

Visual description of the finished product	Pink or dark pink, viscous liquid with crystals presents in suspension
Primary packing material	60mls & 100mls round amber glass bottle with child resistant cap
Secondary packing materials	A printed carton box
Shelf-life and storage condition	36 months, Do not store above 30°C. Do not refrigerate
Route of administration	Oral
Therapeutic indications	Panadol Baby & Infant is an analgesic and antipyretic. – It relieves mild to moderate pain and treatment of fever including headache, muscle ache, sore throat, toothache, earache/otalgia and pain and fever associated with respiratory tract

	infections including cold and flu. – It also relieves fever and pain after vaccination

2. Labelling and product information

Summary of product characteristics
The SmPC included all the relevant information to ensure correct and safe use of the medicine by healthcare providers. The complete SmPC can be accessed here.

Package insert/leaflet
The package insert is confirmed to be derived from the SmPC and contains sufficient data for the end user. Since the product is POM, the package insert contains full prescribing information as per SmPC.

Container labels
The product label information is presented in English. Details in the secondary pack label include:
Brand name: Panadol Baby & Infant

Composition: Paracetamol 120mg/5ml

Pack size: 60 mL and 100 mL

Manufacturing details: batch number, manufacturing date, and expiry date

Storage conditions: Do not store above 30°C. Do not refrigerate

Manufacturer address: physical address of release site

Unique identifier: Not applicable

Special warnings/precautions or instructions for use: Included in the label as can be noted on labels attached

The details of the primary pack include:

Brand name and strength: Panadol Baby & Infant

Manufacturing details: batch number, manufacturing date and expiry date

Name of manufacturer: GlaxoSmithKline Limited

The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up of the product.

Mock labels are appended as annex I.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient

Information on the quality of the API was submitted in form of DMF.

Paracetamol

General Information

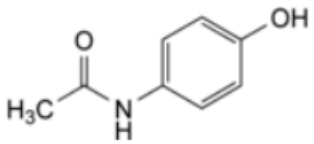
Paracetamol API is compendia in USP, BP, Ph.Eur.

Molecular formula: $C_8H_9NO_2$

Chemical name:

N-(4-Hydroxyphenyl) acetamide

Structure:



General properties

Paracetamol is a white or almost white, crystalline powder sparingly soluble in water, freely soluble in ethanol (96 per cent), very slightly soluble in methylene chloride. The compound displays polymorphism.

As the API is BSC high soluble hence polymorphism and particle size and distribution are considered not of concern.

Manufacture

Paracetamol API manufacturer is Granules India Limited, H.No.6-5 & 6-11 Temple Road, Gummadidala Mandal, Sangareddy District, Bonthapally Village, Telangana, 502313– India and SPECGX LLC, Raleigh Pharmaceutical Plant, 8801 Capital Boulevard, United States Am.- 27616 Raleigh, North Carolina, USA. The manufacturing complies with GMP requirements as evidenced by the GMP certificates issued by the <state the issuing authority>. Paracetamol API is manufactured by chemical synthesis using conventional techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API specifications were set as per <USP/BP/JP/International Ph/in-house> standards and ICHQ3A. The parameters monitored during quality control are: <list the specification tests>. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The <shelf-life/re-test> period of <molecule> API is <number> months when packed in <container closure system> and stored at <storage conditions>.

Quality of the Finished Pharmaceutical Product

Formulation

Panadol Baby & Infant is pink or dark pink, viscous liquid with crystals presents in suspension

Panadol Baby & Infant contains the Paracetamol and other ingredients listed here after: liquid crystallising, sodium ethyl parahydroxybenzoate, sodium methyl parahydroxybenzoate, sodium propylparahydroxybenzoate, sorbitol, anhydrous citric acid, purified water, azotubine, xanthan gum, maltitol syrup, strawberry flavour 70%, sorbitol, and malic acid. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, 8th Edition in terms of function and quantities.

Manufacture

The finished product manufacturers are GlaxoSmithKline Limited, Likoni Road P.O. Box 78392-00507 Nairobi, Kenya. The compliance of the sites to TMDA GMP standards was confirmed through site inspection on dd/mm/yyyy.

Specifications

The FPP is compendia. The manufacturer controls the quality of the finished product as per in-house and ICH requirements. The parameters monitored during quality control are: Description, identification of API and preservatives, relative density, pH, viscosity, 4-aminophenol, preservative efficacy, assay of API and preservatives, and microbiological examination. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on three (3) batches of the finished product stored at 30±2℃ R.H. 75±5% for 36 months and 40±2℃R.H. 75±5% for 6 months. Based on the stability data presented, the approved shelf-life is 24 months when stored in 60mls & 100mls round amber glass bottle with child resistant cap with storage condition ‘Do not store above 30°C. Do not refrigerate’.

Safety and efficacy information

Safety and efficacy of <brand name> was established through <bioequivalence trial/biowaiver application/clinical trial>.
<BE trial/comparative dissolution> report number <number> was submitted.
In case of BE:

Study title		
Study design		
Study site		
Study dates		
Primary objective		
Secondary objective		
Number of participants		
Monitored parameters		
Investigational medicinal products	Test Product	Reference product
	Strength: Batch number: Expiry date:	Strength: Batch number: Expiry date:
Analytical method		
Statistical method		

Efficacy results are summarized as follows:

Parameter	Test	Reference	% Ratio of geometric means	90 % Confidence interval	DF	CV (%)
AUC0-t (units)						
AUC0-inf (units)						
Cmax (units)						

The acceptance limits of 80 – 125% are met by the AUC and Cmax values. Furthermore, the safety profile of the test product is similar to that of reference product. Therefore, <brand name> is equivalent and interchangeable with <comparator>under acceptable in vivo experimental conditions.

In case of biowaiver
The biowaiver was approved based on <BCS classification/additional strength>.

<Brand name> fulfilled the criteriafor waiving an in-vivo bioequivalence study as per relevant TMDA guidance. Dissolution profiles of <Brand name, strength, form> was compared to <comparator name, strength and form>.<At least/less than> 85% of the labelled amount of <molecule> had dissolved in all three media. Therefore, <confirming similarity/necessitating calculation of similarity factor f2, which was noted to be above 50>.

4. Benefit-Risk Assessment and Conclusion

On basis of the data submitted, the current state of knowledge and compliance to Good Manufacturing Practice, the benefit of the product outweighs the risks associated with its use when used in accordance to the summary of product characteristics. Panadol Baby & Infant is recommended for registration.

5. Post-approval updates

Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date

Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response

Re-registration applications

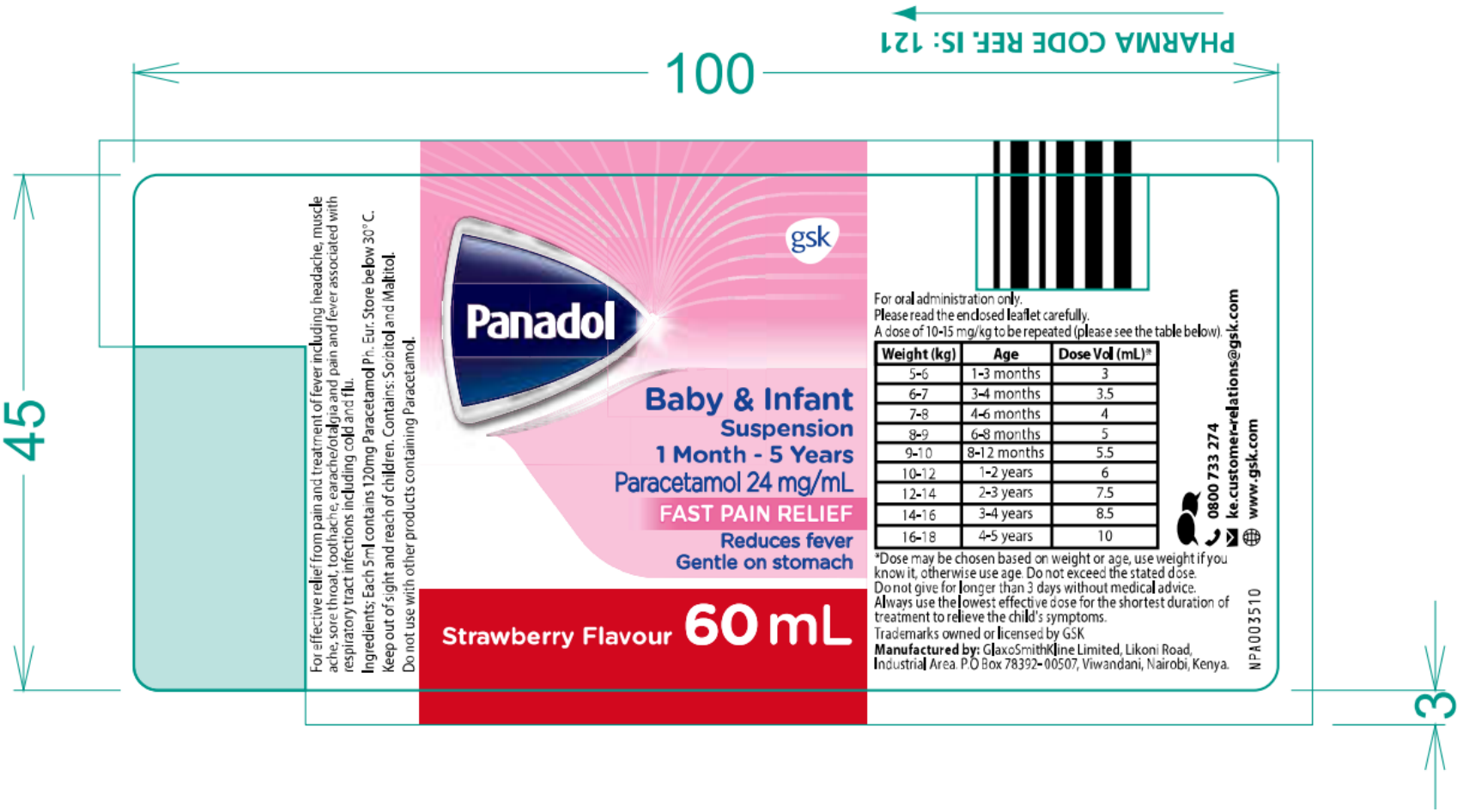
Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Annex I: Mock up labels;

Primary pack label;
100 mL pack label:



Effective date: 03/10/2022

Secondary pack label;

100 mL pack label:

Effective date: 03/10/2022

60 mL pack label:

Effective date: 03/10/2022